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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,556	12/16/1998	SHINICHI KURAKATA	980689/HG	8315

1933 7590 07/15/2003

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
767 THIRD AVENUE
25TH FLOOR
NEW YORK, NY 10017-2023

EXAMINER

OWENS JR, HOWARD V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/15/2003

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/212,556

Applicant(s)

KURAKATA ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Arguments

The following is in response to the amendment filed 4/25/03:

An action on the merits of claims 69 - 77 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 103 and Declaration

Applicant's arguments filed 4-25-03 have been fully considered but they are not persuasive. The rejection of claims 69-77 rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al., EP 0799823 A1 and Ruff et al., Journal of Clinical Investigat., vol. 73, pp. 1483-1486 is maintained for the reasons of record.

Kimura et al., teach the analogous diphenylpyrrole compounds of species 1 of the instant invention. Kimura et al. teach that these compounds as cyclooxygenase-2 inhibitors inhibit prostaglandins. Kimura et al. however does not teach the usefulness of these compounds to treat cachexia or disorders resulting from tumors.

Ruff et al. teach that the inhibition of prostaglandin production counters cachexia or muscle wasting , which adequately bridges the nexus between the differences in the prior art and the invention as claimed.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the diphenylpyrrole compounds of the instant invention to treat cachexia or side effects of tumor related disorders.

A person of ordinary skill in the art would have been motivated to use these art recognized prostaglandin inhibiting diphenylpyrrole compounds to treat cachexia or side effects of tumor related disorders because the prior art has established the usefulness of prostaglandin inhibitors in countering the muscle wasting or cachexia.

The declaration compares Naproxen to the compounds of the invention; however, the declaration is aimed at prior art that is not of record in the instant rejection, specifically Strelkov. To be considered, a declaration should contain statements and/or comparisons to the prior art of record, specifically Kimura in combination with Ruff.

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Applicant's assertion that different factors can lead to cachexia is not probative to the nexus provided by the examiner for the use of the compounds to treat cachexia. One of skill in the art only be provided with a reasonable expectation of success in the use of the compounds to treat cachexia; moreover, the claims are not drawn to symptoms prior to cachexia, but rather the treatment of cachexia, as such applicant's assertion that cachexia formed from one disease pattern is different from cachexia formed from another is not probative. The claims are given the broadest interpretation, as such, the examiner only needs to provide a reasonable motivation to use the compounds as claimed to treat cachexia as supported by the prior art. Note, that reason does not need to be identical to what applicant sets forth to support a conclusion of obviousness.

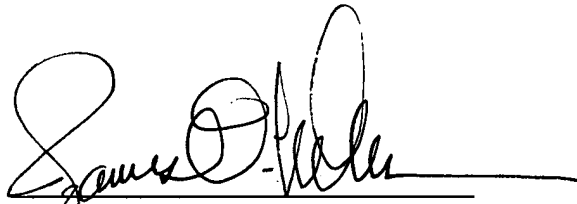
In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant's response attacks Ruff alone, wherein the nexus for combining Ruff in with Kimura is completely silent. As cited above, Kimura et al., teach the analogous diphenylpyrrole compounds of species 1 of the instant invention. Kimura et al. teach that these compounds as cyclooxygenase-2 inhibitors inhibit prostaglandins. Ruff provided the nexus for the use of the compounds to treat cachexia as Ruff teaches that the inhibition of prostaglandin production counters cachexia or muscle wasting. In response to applicant's assertion that the link between prostaglandin inhibitors and muscle wasting can not be generally asserted because Ruff teaches that acetaminophen did not counter muscle wasting, applicant should note, p. 1485, discussion, last paragraph, of Ruff wherein it teaches ".....PG synthesis inhibitors, but not acetaminophen, may be clinically useful in limiting the muscle wasting associated with infection", Thus Ruff does not teach that acetaminophen is a PG inhibitor, it actually sets acetaminophen apart from PG inhibitors in the genus of antipyretic compounds. Given the fact that that Kimura has established the compounds of the invention as PG inhibitors and the prior art has set forth that these PG inhibitors counter muscle wasting, the rejection of record is maintained.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.